UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

JOHN SCHEDIN, Civil No. 08-5743 (JRT)

Plaintiff,

v.

MEMORANDUM OPINION AND ORDER

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.,

Defendant.

Mikal C. Watts, **WATTS LAW FIRM, LLP**, 555 North Carancahua, Suite 1400, Corpus Christi, TX 78478; Ronald S. Goldser, **ZIMMERMAN REED, PLLP**, 651 Nicollet Mall, Suite 501, Minneapolis, MN 55402; and Lewis J. Saul, **LEWIS SAUL & ASSOCIATES**, 183 Middle Street, Suite 200, Portland, ME 04101, lead counsel for plaintiff Schedin.

John Dames and William V. Essig, **DRINKER BIDDLE & REATH LLP**, 191 North Wacker Drive, Suite 3700, Chicago, IL 60606; William H. Robinson, Jr., **LECLAIR RYAN**, 1100 Connecticut Avenue N.W., Suite 600, Washington, DC 20036; and Tracy J. Van Steenburgh, **NILAN JOHNSON LEWIS, PA**, 400 One Financial Plaza, 120 South Sixth Street, Minneapolis, MN 55402, lead counsel for defendant.

Plaintiff John Schedin brought claims against defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho-McNeil") for failure to warn about certain risks he was taking in using its drug, Levaquin, specifically the risk of tendon rupture. Schedin's action was the first case tried from many plaintiffs whose claims have been consolidated for coordinated pretrial proceedings in multi-district litigation. The jury found for Schedin and awarded compensatory and punitive damages. Ortho-McNeil now moves for a new trial claiming the verdicts are against the clear weight of the evidence and that

the defendant was denied a fair trial by erroneous evidentiary rulings and improper closing arguments by Schedin. Ortho-McNeil also moves for judgment as a matter of law ("JMOL") on substantially the same issues as those raised in the motion for a new trial.[1] Ortho-McNeil argues the recent Supreme Court decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), should control the Court's analysis on these motions. Because the Court finds that *Mensing* is inapplicable to a brand-name manufacturer such as Ortho-McNeil, that the verdicts were not against the clear weight of the evidence, and that Ortho-McNeil was not denied a fair trial, the Court denies the motion for a new trial. Further, because the standard of review for JMOL is more stringent than that for a new trial, the Court denies the motion in so far as it rests on the same arguments as the motion for a new trial. As far as the JMOL rests on pre-emption arguments, the Court finds no pre-emption and denies the motion.

BACKGROUND

Plaintiff John Schedin was prescribed Levaquin for an upper respiratory infection in February of 2008 and, after eight days of consuming the drug, he suffered bilateral Achilles tendon ruptures. (Compl. ¶ 108, Docket No. 1.) At the time Schedin was prescribed Levaquin, the drug contained a warning regarding tendon rupture that stated:

> **Tendon effects**: Ruptures of the shoulder, hand, Achilles tendon, or other tendons that required surgical repair or resulted in prolonged disability have been reported in patients receiving quinolones, including levofloxacin. Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant corticosteroids, especially in the elderly.

[1] The JMOL motion is Ortho-McNeil's third. The Court denied its two previous motions. (Docket Nos. 179, 196.)

(Def. Trial Ex. 12.) Schedin brought claims against Ortho-McNeil, arguing the label was inadequate to warn his physician of the risks of Levaquin related to tendon injuries. Schedin sought both compensatory and punitive damages. He also alleged violations of Minnesota's Consumer Fraud Act. *See* Minn. Stat. § 325F.69. On December 8, 2010, a jury found for Schedin on his failure to warn claim – awarding him compensatory damages of $700,000 and punitive damages of $1,115,000. (Docket Nos. 183, 184.) The jury found for Ortho-McNeil on the consumer fraud claim.

ANALYSIS

I. DUTY TO WARN AFTER *MENSING*

As an initial matter, Ortho-McNeil submitted a letter to the Court arguing that the Supreme Court decision in *Mensing*, issued after briefing on the instant motions, should dictate the outcome of these motions. (Docket No. 257.) *Mensing* discussed pre-emption in the context of prescription drugs. Pre-emption is the application of the Supremacy Clause of the U.S. Constitution,[2] resulting in the rule that any "state law that conflicts with federal law is without effect." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (internal quotation marks omitted). "Preemption is disfavored in areas of historic importance to the states' police powers – areas such as public health and safety." *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. 01-MDL-1396, 2004

[2] The Supremacy Clause provides that "the Laws of the United States . . . shall be the supreme Law of the Land . . . ." U.S. Const. art. VI, cl. 2.

WL 45503, at *5 (D. Minn. Jan. 05, 2004) (citing *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000)).

Pre-emption can be either express or implied. Express pre-emption is found when Congress "pre-empt[s] state law by so stating in express terms." *Hillsborough Cnty., Fla. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 712-13 (1985) (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Express pre-emption is not at issue in this case.

However, where Congress has not expressly pre-empted state law, a court will infer implied pre-emption "where it is impossible for a private party to comply with both state and federal law, and where under the circumstances of a particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat. Foreign Trade Council*, 530 U.S. 363, 372-73 (2000) (alterations, citations, and internal quotation marks omitted). Therefore, "a conflict arises when compliance with both federal and state regulations is a physical impossibility . . . ." *Automated Med. Labs, Inc.*, 471 U.S. at 713 (internal quotations omitted). "Impossibility pre-emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 118, 1199 (2009).

The *Mensing* Court held that a generic drug manufacturer meets the burden of impossibility pre-emption for state failure to warn claims by showing that it could not "independently satisfy those state duties" due to its position in the Food and Drug Administration's ("FDA") regulatory scheme. *Mensing*, 131 S. Ct. at 2581. Under *Mensing*, Ortho-McNeil argues Schedin's claims against it are pre-empted since they

required "independent action" by the FDA. This "independent action" standard of *Mensing*, however, is not controlling for several reasons.

First, the Supreme Court noted that its finding of impossibility pre-emption of state law failure to warn claims for generic manufacturers did **not** apply to brand-name manufacturers. Rather, the *Mensing* Court explicitly affirmed its previous ruling in *Wyeth* that failure to warn claims against brand-name manufacturers are not pre-empted.[3] *Mensing*, 131 S. Ct. at 2581 ("We recognize that from the perspective of [plaintiffs], finding pre-emption here but not in *Wyeth* makes little sense. **Had [plaintiffs] taken . . . the brand-name drug prescribed by their doctors, *Wyeth* would control and their lawsuits would not be pre-empted**.") (emphasis added). Since Levaquin is a brand-name drug, the pre-emption analysis of *Wyeth*, not *Mensing*, controls.

Secondly, the manner in which the *Mensing* Court defined the duty of generic manufacturers – to maintain exactly the same label as the brand-name product – implies a heightened duty for brand-name manufacturers since the brand-name manufacturers are the only entities that **ever** would be able to initiate a label change during the relevant time periods. In both *Wyeth* and *Mensing*, as in the instant case, the FDA regulations at the time of the contested prescription did not empower the FDA to require label changes of manufacturers. *See Mensing*, 131 S. Ct. at 2588 n.9 (Sotomayor, J., dissenting). In 2007, the FDA was given that authority. Pub. L. 110-85, § 901, 121 Stat. 924-26. However, under the pre-2007 statutory framework applicable to *Wyeth*, *Mensing*, and this case, a

[3] Had the *Mensing* Court not expressly affirmed *Wyeth*, the Court still would be obliged to read them in concert with each other; the cases were decided a mere two years apart.

brand-name manufacturer was the only entity in the trifecta of actors (the FDA, the brand-name manufacturer, and the generic) that could strengthen an inadequate label.[4]

Congress and the FDA have always been clear, however, that they want warnings strengthened when necessary. The FDA requires that warnings "shall describe adverse reactions and potential safety hazards [and] limitations in use imposed by them . . . ." 21 C.F.R. § 201.57(e) (2001). Manufacturers are required to develop post-market risk identification and analysis systems. 21 U.S.C. § 355(k). Furthermore, since risks associated with a drug may accumulate over time, manufacturers

> must keep records of clinical experiences . . . [,] record and report certain adverse events to FDA, and must also annually report a "summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product" and a "description of actions the applicant has taken or intends to take as a result of this new information."

Brief for the Unites States as Amicus Curiae Supporting Respondents at *5-6, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 741927 (2011) [hereinafter "U.S. Amicus Brief"] (citing various applicable FDA regulations).

Unlike these clear mandates applicable primarily to brand-name manufacturers, the *Mensing* Court found the FDA regulations only empowered a generic manufacturer to **ask** the FDA to **ask** the brand-name manufacturer to change the label. Since "requesting FDA assistance would have satisfied the [generic m]anufacturers' federal duty [to advise the FDA of adverse events, but] would not have satisfied their state tort-law duty to

[4] The FDA, prior to 2007, could withdraw the permission to market a brand-name drug if it believed the labeling was inadequate. 21 U.S.C. § 355(e) (2006); *Mensing*, 131 S Ct. at 2588 n.9 (Sotomayor, J., dissenting).

provide adequate labeling[,]" claims premised on the manufacturers' failure to make such a request were pre-empted. *Mensing*, 131 S. Ct. at 2578. Brand-name manufacturers under the FDA's pre-2007 regime, however, did not face the same constraints since they could strengthen a label without prior FDA approval. "It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers." *Id.* at 2582. As a result, "[t]he need for [subsequent] FDA approval of the label change [for brand-name manufacturers] did not make compliance with federal and state law impossible in every case." *Id.* at 2588 (Sotomayor, J., dissenting).

Given the power to initiate a label change that a brand-name manufacturer had in the pre-2007 FDA regulatory scheme, the *Wyeth* Court held that a brand-name manufacturer had to demonstrate by "clear evidence" that the FDA would **not** have approved a change to the label in order to demonstrate impossibility pre-emption. *Wyeth*, 129 S. Ct. 1198. While the *Wyeth* Court did not elaborate on what type of evidence would clearly establish the FDA would not approve a label change, the *Mensing* Court noted that the brand-name manufacturer in *Wyeth* "could have attempted to show, by 'clear evidence,' that the FDA **would have rescinded any change in the label** and thereby demonstrate that it would in fact have been impossible to do under federal law what state law required." *Mensing*, 131 S. Ct. at 2581 n.8 (emphasis added) (citing *Wyeth*, 129 S. Ct. 1198). Taken together, *Wyeth* and *Mensing* stand for the proposition that to trigger pre-emption, a brand-name manufacturer must show that the FDA would not have approved a proposed label change that is the basis for a state law failure to warn

claim; indeed, the brand name manufacturer likely must proffer evidence of the FDA's **rejection of an actual label change**. *See id.* Such a rejection was not in evidence in *Wyeth*, nor in the instant case.

Ortho-McNeil, in its post-briefing letter to the Court, submitted **for the first time** a letter from the FDA dated April 20, 2008, that it claims is clear evidence that the FDA would not have approved a label change prior to Schedin's prescription. (Letter, Ex. 2, Docket No. 257.) The letter, **not in evidence at trial**, is a response to a May 2005 Citizen's Petition to strengthen the label of Levaquin regarding tendon rupture and summarizes the literature review of three studies conducted between 2005 and 2007 (including the Ingenix study in which Ortho-McNeil participated). In the letter, the FDA concludes that "these 3 studies do not provide data to suggest a robust difference in the risk for tendon rupture between [fluoroquinolones]." *Id.* at 1. However, that letter was written at a time when the FDA had the authority to **require** a label change. Furthermore, it was not a response to a manufacturer's proposed label change. The United States' amicus brief in *Mensing* is instructive on this distinction:

> Indeed, it would be both paradoxical and contrary to FDA's statutory responsibilities for FDA to insist upon a labeling revision under a certain standard – 'reasonable evidence of an association of a serious hazard with a drug,' – and then fail to respond positively to a warning proposed in conformity with that standard.

U.S. Amicus Brief at *25 (citing 21 C.F.R. § 210.57(e) (2001)). As a result, the Court finds the letter from the FDA falls short of the clear evidence standard, even if it had been properly a part of the trial record. That the FDA did not require a label change, after it received the statutory authority to do so, in the face of a Citizen's Petition, not supported

by the manufacturer does not constitute clear evidence that the FDA would have **rejected** a label change proposed by Ortho-McNeil before Schedin was prescribed Levaquin.

As discussed more thoroughly later in this Order, Ortho-McNeil asserts that the fact it would have had to apply for a waiver to include comparative toxicity information in Levaquin's label supports its argument that these motions should be evaluated under the "independent action" standard of *Mensing*.[5] However, given the heightened standard for brand-name manufacturers to establish pre-emption, and the likelihood that "clear evidence" requires a rejection of a label change actually proposed under the previous statutory framework, the same would hold true for comparative toxicity label changes. Had Ortho-McNeil applied for a waiver from the "well-controlled studies" requirement that the FDA rejected, it would possess clear evidence in its favor. It does not.

The *Mensing* Court rationalized the differing standards for generic and brand-name manufacturers in part on the fact that most problems associated with a drug will become evident during the patent period for a drug. "[G]enuinely new information about drugs in long use (as generic drugs typically are) appears infrequently . . . because patent protections ordinarily prevent generic drugs from arriving on the market for a number of years after the brand-name drug appears." *Mensing*, 131 S. Ct. at 2581 n.9 (citations and internal quotation marks omitted). Accordingly, a heightened duty for a brand-name

[5] The FDA requires either an "adequate and well-controlled stud[y]" or a waiver from this requirement when a manufacturer intends to make statements in the "[i]ndications and usage" section of the label comparing the safety or effectiveness of the drug with other agents for the same indication. 21 C.F.R. § 201.57(c)(2)(iii). Greater discussion of this regulation as it applies to the instant litigation can be found in *Schedin v. Ortho-McNeil-Janssen Pharm., Inc.*, No. 08-5743, 2011 WL 834020, at *5-7 (D. Minn. Mar. 4, 2011).

manufacturer makes practical sense. The brand-name manufacturer must be vigilant for problems and provide adequate labeling during the patent life of its drugs. For all these reasons, the Court finds that the motions at issue here are most properly evaluated under the heightened duty the *Wyeth* and *Mensing* Courts have articulated for brand-name manufacturers. *Mensing* does not, as Ortho-McNeil argues, dictate judgment as a matter of law on the grounds of federal pre-emption. The Court now turns to the instant motions.

II. MOTION FOR A NEW TRIAL

Under Rule 59(a) of the Federal Rules of Civil Procedure, the Court may grant a motion for a new trial "on all or some of the issues . . . ." Fed. R. Civ. P. 59(a)(1). "A new trial is appropriate when the first trial, through a verdict against the weight of the evidence . . . or legal errors at trial, resulted in a miscarriage of justice." *Gray v. Bicknell*, 86 F.3d 1472, 1480 (8th Cir. 1996). "The authority to grant a new trial is within the discretion of the district court." *Id.* Ortho-McNeil argues it is entitled to a new trial since the clear weight of the evidence did not support the verdict, the Court made erroneous evidentiary rulings, and Schedin made improper arguments in closing during the punitive damages phase, requiring a new trial on Ortho-McNeil's liability.

A. Clear Weight of the Evidence

With regard to the weight of the evidence, a new trial is warranted if "the verdict was against the great, clear, or overwhelming weight of the evidence." *Frumkin v. Mayo Clinic*, 965 F.2d 620, 625 (8th Cir. 1992). Further, only if the jury's verdict is so against

the great weight of the evidence that it constitutes a miscarriage of justice should a motion for a new trial should be granted. *Ogden v. Wax Works, Inc.*, 214 F.3d 999, 1010 (8th Cir. 2000). In other words, there is a miscarriage of justice when there is insufficient evidence to support a verdict. *Douglas Cnty. Bank & Trust Co. v. United Fin. Inc.*, 207 F.3d 473, 478 (8th Cir. 2000). "On a motion for new trial, the district court is entitled to interpret the evidence and judge the credibility of witnesses, but it may not usurp the role of the jury by granting a new trial simply because it believes other inferences and conclusions are more reasonable." *Manus v. Am. Airlines, Inc.*, 314 F.3d 968, 973-74 (8th Cir. 2003) (internal quotation marks omitted); *see also Harris v. Sec'y, U.S. Dept. of the Army*, 119 F.3d 1313, 1318 (8th Cir. 1997) ("In determining whether a verdict is against the weight of the evidence, the trial court . . . can weigh the evidence, disbelieve witnesses, and grant a new trial even where there is substantial evidence to sustain the verdict. The district court, however, may not reweigh the evidence and set aside the jury verdict merely because the jury could have drawn different inferences or conclusions or because judges feel that other results are more reasonable." (internal quotation marks and citations omitted)).

Ortho-McNeil argues that the jury's verdict on Schedin's failure to warn claim is against the clear weight of the evidence because Schedin failed to prove that the Levaquin label was inadequate to communicate the risks of tendon disorders. Ortho-McNeil also argues that the verdict contravened the weight of the evidence because information regarding the comparative toxicity of other fluoroquinolones, information Schedin alleged rendered the label inadequate, did not exist with scientific certainty.

Finally, Ortho-McNeil argues the punitive damages award is not supported by the clear weight of the evidence since it took several affirmative steps to enhance the Levaquin warning based on events in Europe, thereby negating a finding of deliberate disregard.

1. Inadequacy of the label

Ortho-McNeil argues that Schedin failed to prove the label was inadequate and points to the fact that the Levaquin label has contained warnings related to tendon ruptures since 1997 when it was first marketed in the United States. Ortho-McNeil updated the label in 2001 to indicate that the tendon rupture risk was greater for those taking concomitant corticosteroids and the elderly. Schedin's prescribing physician, Dr. Beecher, testified that he read the Levaquin label when he first began prescribing it, and that he was aware of information including the general tendon warning in the earliest Levaquin label. (Trial Tr. at 1090:9-17, Nov. 19, 2010.) He also testified, however, that he did not read the revised label prior to his prescription to Schedin and thus was unaware of the increased warning for the elderly and those taking concomitant corticosteroids. (*Id.* at 1106:23-1107:11.) Moreover, Beecher testified that he no longer prescribes Levaquin unless a patient demands it. (*Id.* at 1098:08-10 (Q: Okay. In your deposition, did you say you don't give [Levaquin] anymore unless somebody pretty much demands it? A: It's true.").) Furthermore, Schedin presented evidence that sales representatives did not communicate the label change to Beecher, despite Ortho-McNeil's argument that Beecher simply did recall such communications. (*See, e.g.*, *id.* at 1016-19 (related to the sales calls of Monica Sadar).)

Ortho-McNeil relies on case law supporting the proposition that warnings are adequate as a matter of law when a plaintiff has not identified a piece of information that would have convinced the prescribing physician to alter his treatment regimen. *See, e.g.*, *Greiner v. Sofamor, S.N.C.*, No. 4-95-645, 1999 WL 716891, at *5 (D. Minn. Mar. 8, 1999). However, the jury could infer from the fact that Beecher no longer prescribes Levaquin that **some** piece of information would have altered his prescribing decision since, in fact, he has changed his prescribing patterns as a result of his increased awareness of the risks of the drug. Therefore, *Sofamor* is unavailing.

Ortho-McNeil next argues that since Beecher admitted he had not read the Levaquin label in effect at the time of the Schedin's prescription in 2005, no additional information in that label could have altered his prescribing decision, breaking the causal chain. *See Johnson v. Zimmer, Inc.*, No. 02-1328, 2004 WL 742038, at *9 (D. Minn. Mar. 31, 2004) ("[W]here an adequate warning could not have prevented a plaintiff's injuries, causation does not exist as a matter of law."). In *Zimmer*, the prescribing doctor testified that "he had never, in any context, seen the warnings provided . . . ." *Id.* at *10. In contrast here, Beecher had read the original warning and worked with a team of doctors with whom he often discussed patients and outcomes. (Trial Tr. at 1093-94, Nov. 19, 2010.) To hold, as a matter of law, that causation does not exist in a situation where the prescribing doctor read and was aware of an initial warning and worked with other doctors who could have read the more updated label, is an unwarranted extension of *Zimmer*.

It also fails to account for the U.S. Supreme Court holding that "the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth*, 129 S. Ct. at 1197-98. While it is true that, in this case, a differently worded warning in the package label **alone** may not have altered Beecher's choice of drug, the gravamen of Schedin's case was that Ortho-McNeil did not take various reasonable measures, including but not limited to a stronger label, to ensure the communication of any enhanced warning. The *Mensing* Court noted, for example, that "Dear Doctor letters qualify as 'labeling.'" 131 S. Ct. at 2576. Hence, the wording in the package label by itself cannot disrupt the jury's verdict with regard to the adequacy of the warning.

The duty to warn rests on the manufacturer such that the manufacturer must do just that – warn. The jury found that fine print changes to the label of a drug that had been on the market for years with no other communication to prescribers failed to fulfill that duty. The Court finds that the jury had sufficient evidence from which to conclude Ortho-McNeil breached its duty to warn and that this breach caused Schedin's injuries. Therefore, under the standard for granting a new trial, the verdict was not against the great weight of the evidence such that it constitutes a miscarriage of justice. *See Ogden*, 214 F.3d at 1010.

2. Comparative toxicity

Ortho-McNeil argues that the clear weight of the evidence does not support a finding that it owed a duty to provide comparative toxicity information for Levaquin and

other fluoroquinolones.[6] Recapping extensively the testimony of its own experts, Ortho-McNeil concludes that the volume of expert testimony demonstrates there was not reasonable evidence that Levaquin was more tendon toxic than other fluoroquinolones. It challenges the nature of the scientific evidence that Schedin's experts utilized, arguing adverse event reports ("AER") and case studies are not reliable for establishing an association or causality, as explained by Ortho-McNeil's expert Peter Layde. (Trial Tr. at 2215:12-2216::14, Nov. 30, 2010.) However, Schedin's expert, Gregory Bisson, relied on AERs and cases studies in part to offer his opinion that a greater tendon toxicity exists. (Trial Tr. at 257:6-283:4, Nov. 16, 2010.) Ortho-McNeil never raised a motion to exclude Bisson's testimony prior to trial and, while it objected to the admission of AERs as hearsay, Bisson's use of AERs in forming his opinions comports with the rules of evidence. *See* Fed. R. Evid. 703 ("If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted.").

Essentially, Ortho-McNeil argues the Court should afford more weight to the opinions of its witnesses that Levaquin is not more tendon toxic than other fluoroquinolones and that even if it is, such a determination was not evident at the time of Schedin's prescription. However, given the admissibility of the evidence proffered by Schedin's experts, to order a new trial on this basis would usurp the role of the jury in the

[6] Ortho-McNeil's pre-emption arguments regarding comparative toxicity are discussed below in relation to its motion for judgment as a matter of law.

a manner not within the discretion of the Court on a motion for a new trial. *See Manus*, 314 F.3d at 973-74.

3. Punitive damages

Ortho-McNeil argues the punitive damages award was against the clear weight of the evidence in large part because the standard for awarding punitive damages is a higher standard than for underlying liability. *See* Minn. Stat. § 549.20, subd. 1(a) ("Punitive damages shall be allowed in civil actions only upon clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others."). However, on a motion for a new trial, the Court applies the same standard of review regardless of the underlying burden on the plaintiff, and must view the evidence in a light most favorable to the jury verdict. *Inacom Corp. v. Sears, Roebuck and Co.*, 254 F.3d 683, 689 (8th Cir. 2001) ("The strictures of the review process dictate that we view the evidence [on punitive damages] in a light most favorable to the jury's verdict. Reversible error occurs only when there is a complete absence of probative facts to support the conclusion reached." (alteration and internal citations omitted)).

Here, Schedin presented evidence that Ortho-McNeil knew of the potential for higher tendon toxicity of Levaquin (*see* Pl.'s Ex. 88 (letter to the FDA discussing knowledge of Ortho-McNeil in October of 2001)), assisted in the design of a study allegedly to hide that potential and cloud the field of academic literature on the topic (*see* Pl.'s Ex. 14 (meeting minutes discussing changes to the Ingenix study so as to protect the U.S. market)), and then failed to adequately warn prescribers as discussed above. From this, the jury had sufficient evidence to determine that Ortho-McNeil had deliberately

disregarded the rights and safety of others to warrant an award of punitive damages. The Court declines to draw different inferences from the evidence as urged by Ortho-McNeil. *See Harris*, 119 F.3d at 1318.

B. Erroneous Evidentiary Rulings

The Court may also grant a new trial where improper evidentiary rulings "had a substantial influence on the jury's verdict[,]" *Littleton v. McNeely*, 562 F.3d 880, 888 (8th Cir. 2009) (internal quotation marks omitted), and the admission of evidence was "so prejudicial that a new trial would likely produce a different result." *Harrison v. Purdy Bros. Trucking Co., Inc.*, 312 F.3d 346, 351 (8th Cir. 2002) (internal quotation marks omitted). Erroneous evidentiary rulings do not warrant a new trial unless they affected the substantial rights of the parties. Fed. R. Civ. P. 61;[7] *Anderson v. Genuine Parts Co., Inc.*, 128 F.3d 1267, 1270 (8th Cir. 1997); *Norton v. Caremark, Inc.*, 20 F.3d 330, 338 (8th Cir. 1994). Ortho-McNeil objects specifically to three evidentiary rulings of the Court that it claims created undue prejudice: the admission of evidence pertaining to post-2005 Levaquin label changes, the admission of evidence pertaining to foreign regulatory actions, and the admission of evidence related to AERs.

[7] Rule 61 of the Federal Rules of Civil Procedure provides:

> Unless justice requires otherwise, no error in admitting or excluding evidence – or any other error by the court or a party – is ground for granting a new trial, for setting aside a verdict, or for vacating, modifying, or otherwise disturbing a judgment or order. At every stage of the proceeding, the court must disregard all errors and defects that do not affect any party's substantial rights.

1. Post-2005 Labeling

At trial, Ortho-McNeil objected to the admission of evidence of post-2005 labeling of Levaquin, asserting that such evidence should have been excluded as a subsequent remedial measure, *see* Fed. R. Evid. 407, and that the jury would be unduly prejudiced by such evidence to conclude that pre-2005 labeling was de facto inadequate.[8] The Court found the evidence admissible since "[a]n exception to Rule 407 is recognized for evidence of remedial action mandated by superior governmental authority . . . ." *In re Levaquin Prods. Liab. Litig.*, Nos. 08-1943, 08-5743, 2010 WL 4882595, at *1 (D. Minn. Nov. 24, 2010). To address any potential prejudice, the Court gave the jury a limiting instruction.[9] The Court finds the admission of the evidence was not erroneous under Rule 407 and any potential harm or prejudice was sufficiently mitigated by the Court's limiting instruction to the jury on the issue. *See Gen. Indus. Corp. v. Hartz Mountain Corp.*, 810 F.2d 795, 808 (8th Cir. 1987) ("Admission of evidentiary matters is

[8] Schedin took Levaquin in 2005.

[9] The post-2005 labeling limiting instruction read as follows:

> You have heard evidence that the Food and Drug Administration ("FDA") approved Levaquin as safe and effective for its intended uses, that the FDA approved Levaquin's label or "package insert" in place at the time of plaintiff's prescription, and that the FDA required changes to the label in 2008 after the time of plaintiff's prescription. You may consider that evidence, along with all of the other evidence presented, in evaluating whether plaintiff has proven his claims by a preponderance of the evidence. Neither the FDA's approval of the drug and its label, nor its requirement of label changes, is necessarily conclusive or controlling on any issue you have been asked to decide. You may give it as much or as little weight as you think it deserves, in light of all the evidence, under the law as set forth in these instructions.

(Jury Instructions at 15, Docket No. 176.)

within the discretion of the trial court and will not be disturbed on appeal unless abuse of that discretion is shown. . . . Moreover, the limiting instruction given by the district court sufficiently informed the jury of the restrictions on its use of the [evidence].”). Finding no error in the admission of the evidence, the Court concludes that no substantial rights were affected to warrant a new trial.

2. Foreign Regulatory Action

At trial, Ortho-McNeil objected to the admission of foreign regulatory action related to Levaquin, arguing that such evidence was hearsay, irrelevant, and highly prejudicial. The Court admitted this evidence as it was being offered for the purposes of notice and motive. *In re Levaquin Prods. Liab. Litig.*, Nos. 08-1943, 08-5743, 2010 WL 4676973, at *5 (D. Minn. Nov. 9, 2010). The Court noted that Schedin’s evidence was not final foreign regulatory action, which courts have deemed potentially prejudicial given differing regulatory schemes. *Id.* (citing *In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1315 (M.D. Fla. 2009); *In Re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007)). Paradoxically, Ortho-McNeil submitted evidence of final foreign regulatory action at trial. (Def.’s Ex. 123.) Further, Ortho-McNeil argued such evidence **was** probative of the underlying adequacy of its U.S. label. (Trial Tr. at 3029:14-24 (“[I]n October 2003, the final report . . . by the MHRA assessor . . . found that tendon warnings in Europe which mirrored, pretty much mirrored the tendon warnings that were put out by Ortho-McNeil in the United States were adequate.”).)

Since a core argument of Schedin’s case was that Ortho-McNeil knew of the higher tendon toxicity of Levaquin because of its experiences in Europe and that it took

inappropriate actions to protect its share of the U.S. market as a result, the Court finds that admission of the documents between foreign regulators and Ortho-McNeil were relevant to notice and motive. Ortho-McNeil argues it is entitled to a new trial because the admission of this evidence "encouraged jurors to defer to the judgments of foreign regulators." (Mem. in Supp. at 28, Docket No. 226.) However, foreign regulators did not require any label changes; to the extent that this evidence may have encouraged jurors to defer, it arguably would have done so in favor of Ortho-McNeil. Additionally, the Court mitigated any potential prejudice with a limiting instruction to the jury on the proper use of such evidence.[10] *See Gen. Indus. Corp.*, 810 F.2d at 808. As a result, the Court denies a new trial on the basis of its evidentiary ruling relating to foreign regulatory action.

3. AERs

At trial, Ortho-McNeil objected to the discussion of AERs regarding Levaquin, arguing that such evidence was not reliable to show causation. The Court had denied its previously filed motion in limine regarding AERs, finding that the evidence was

[10] The foreign regulatory action limiting instruction read as follows:

> You have heard evidence on various regulatory issues that occurred outside of the United States. The legal standards used by foreign regulatory agencies may be different from those used in the United States. Therefore, you should not use regulatory actions by foreign regulatory agencies to determine whether or not defendant abided by or violated any legal duty in the United States. However, the evidence surrounding these foreign regulatory events may be considered by you as a basis for understanding defendant's actions in the United States, defendant's notice about issues that were relevant in the United States, and defendant's motives in responding to those issues which may have impact within the United States.

(Jury Instructions at 16, Docket No. 176.)

admissible to show notice and could also support a finding of causation. *In re Levaquin Prods. Liab. Litig.*, 2010 WL 4676973, at *4. The Court noted that AER databases are commonly used by experts in the field to determine causation in conjunction with other evidence. *Id.* Ortho-McNeil moves for a new trial primarily based on the conclusions drawn by Bisson that the AERs and other evidence demonstrated a higher tendon toxicity for Levaquin. However, the bases of Bisson's opinions were permissible under Rule 703, as explained above, and he was subject to vigorous cross examination by Ortho-McNeil. Ortho-McNeil also presented its own experts who challenged Bisson's conclusions. (*See generally* Trial Tr. at 2202-2322, Nov. 30, 2010, Docket No. 206 (testimony of defense expert Dr. Peter Layde); Trial Tr. 2807-2897, Dec. 2, 2010, Docket No. 208 (testimony of defense expert Dr. George Holmes).) Finally, the Court issued a limiting instruction to the jury to mitigate any potential prejudice from the jury viewing AERs as causation evidence standing alone.[11] The Court finds the admission of this evidence was not error,

[11] The AERs limiting instruction read as follows:

> You have heard testimony and have seen exhibits relating to case reports, case series, spontaneous reports, and adverse events reporting injuries in persons who have taken Levaquin. This type of information alone should not be considered by you as evidence of a causal relationship between use of the drug and the injury, but may be considered along with other evidence to determine whether the drug is a substantial contributing factor to the injury. These reports may be considered as one type of evidence of a signal that there may be an association between a drug and the adverse event.
>
> Likewise, this type of information or data alone should not be considered by you as evidence of the incidence of the injury associated with the drug, or evidence of making comparisons between drugs.
>
> Simply because one drug may have more reports of a particular injury, is not evidence that it presents more of a risk of that injury than other drugs.

(Footnote continued.)

and any prejudice was mitigated by both cross examination and the limiting instruction. *See Gen. Indus. Corp.*, 810 F.2d at 808.

C. Improper Closing Arguments

"[W]hen a new trial motion is based on improper closing arguments, a new trial should be granted only if the statements are 'plainly unwarranted and clearly injurious' and 'cause prejudice to the opposing party and unfairly influence a jury's verdict.'" *Harrison*, 312 F.3d at 351 (alternations omitted) (citing *Alholm v. Am. Steamship Co.*, 144 F.3d 1172, 1181 (8th Cir. 1998). Ortho-McNeil asserts that the punitive damages award reflects passion and prejudice on the part of the jury since the award is out of line with the jury's finding of no liability on the Consumer Fraud Act claim. Ortho-McNeil claims the award is a direct result of improper arguments on the part of Schedin's counsel during the punitive damages phase of the trial. Since the majority of the evidence considered by the jury was presented during the liability phase of the trial,[12] Ortho-McNeil asserts the Court should order a new trial on the underlying claims to redress the prejudice in the punitive damages closing arguments. Ortho-McNeil stresses Schedin's closing arguments were improper on three bases: Schedin encouraged the jury to award

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(Footnote continued.)

> Epidemiologists consider such evidence together with more formal studies and other factors in deciding whether there is causation.

(Jury Instructions at 14, Docket No. 176.)

[12] During the punitive damages phase, little new evidence was introduced with the exception of sales revenue figures for Levaquin from 1997-2009, offered by Schedin, and each party gave closing arguments on punitive damages.

damages for conduct unrelated to his injuries, urged the jury to speculate about Ortho-McNeil's profits, and misrepresented the evidence.

1. Conduct unrelated to injuries

In the context of punitive damages, "[a] defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages. A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003). Ortho-McNeil asserts that Schedin urged the jury to consider actions after Schedin's prescription, sales aids that were never seen by Beecher directly, and Ortho-McNeil's studies on Levaquin and children as a means to extend its patent. Further, it argues that Schedin improperly used an Abraham Lincoln quote from the Gettysburg Address.

First, Schedin did discuss the 2008 enhanced "black box" warning in closing. However, he did so only in the context of characterizing Ortho-McNeil's attitude towards increasing the warnings associated with Levaquin as consistent with its behavior **prior** to Schedin's injury. (Trial Tr. at 3202:21-23, Dec. 8, 2011, Docket No. 212 ("[T]hey studied it and figured out that a black box and a Dear Doctor letter would cost them 15 percent of their sales volume.").) This discussion of the black box is directly related to Schedin's theory of underlying liability. *See Campbell*, 538 U.S. at 422-23.

Second, Beecher testified that he never saw sales aids. However, Schedin's failure to warn claim rested in part on the casual nexus of Ortho-McNeil's failure to warn the medical community at large, on which Beecher relied for information. As a result, the

discussion of sales aids and the absence of reference to tendon injuries and the co-administration of corticosteroids is not independent from the acts upon which liability was premised. *See id.*

Third, Schedin referenced Ortho-McNeil's scientific studies on Levaquin and children so as to discredit Ortho-McNeil's expert Noel who testified as to Ortho-McNeil "doing good things about kids." (*Id.* at 3195:25-3196:6.) The impugning of a witness, through reference to evidence, is proper fodder for closing argument. *See, e.g.*, *United States v. Franklin*, 568 F.2d 1156, 1158-59 (8th Cir. 1978).

Fourth, Schedin's use of a quote from the Gettysburg Address, while possibly an ill-fitted analogy, does not rise to the level of prejudicial argument that would incite the passion of the jury. Minnesota courts have found reference to irrelevant personal characteristics of the plaintiff an inappropriate appeal to the jury's prejudice and sympathy. *See, e.g.*, *Jenson v. Peterson*, 264 N.W.2d 139, 145 (Minn. 1978) (finding improper discussion of the plaintiff's physical disabilities that were unrelated to the contract dispute at issue). However, analogies to general societal experiences do not usually constitute prejudicial error. *See, e.g.*, *Hall v. Luebbers*, 341 F.3d 706, 719 (8th Cir. 2003) (finding no prejudice where the prosecutor, in closing, referenced war and courage and "commented about the fear of society as a whole and how this case would affect anyone presented with the same situation"). The Court finds the Civil War distant enough in history so as to not incite the personal passions of the jurors in this case. *Cf. United States v. Steele*, 390 Fed. App'x 6, 15 (2d Cir. 2010) (noting no prejudice in discussion of Al Qaeda in a racketeering case despite characterizing the comments as a

"blatant and improper ploy to evoke images of terrorists so soon after the attacks of September 11, 2001" (referencing *United States v. Burden*, 600 F.3d 204 (2d Cir. 2010)). In sum, the Court finds Schedin's closing arguments did not arouse such passion and prejudice in the jury, nor were they so removed from issues regarding the liability incurring actions of Ortho-McNeil, so as to warrant setting aside the punitive damages award and ordering a new trial. *See Harrison*, 312 F.3d at 351.

2. Speculation about profits

Ortho-McNeil argues Schedin's reference to profits from the sale of Levaquin required the jury to speculate improperly. Minnesota's punitive damages statute allows a jury to consider a list of factors that is not exclusive. Minn. Stat. § 549.20, subd. 3 ("Any award of punitive damages shall be measured by those factors which justly bear upon the purpose of punitive damages, **including** . . . the financial condition of the defendant . . . ." (emphasis added)). Ortho-McNeil asserts that the statute allows the jury to consider the net worth of a defendant but not the profit from a single product. The Court finds no support for such a proposition from the inclusive nature of the statutory language. Minnesota courts have allowed lost profits to be considered in punitive damages awards. *See, e.g., Hydra-Mac, Inc. v. Onan Corp.*, 430 N.W.2d 846, 855 (Minn. Ct. App. 1988), *rev'd on other grounds*, 450 N.W.2d 913 (Minn. 1990). Accordingly, the Court finds earned profits suitable for consideration and supported by adequate evidence. (Trial Tr. 3158:8-13, Dec. 8, 2011, Docket No. 212.) Furthermore, the Court gave the jury a limiting instruction to not speculate when determining punitive damages. (Supp. Jury Instructions, Docket No. 180.) As a result, the Court does not find the mention of profits

in Schedin's closing arguments incited such passion and prejudice so as to justify overturning the award and granting a new trial. *See Harrison*, 312 F.3d at 351.

3. Misrepresenting evidence

Ortho-McNeil argues that Schedin misrepresented evidence in a manner that was "plainly unwarranted and clearly injurious." *See Griffin v. Hilke*, 804 F.2d 1052, 1057 (8th Cir. 1986). First, it argues Schedin misrepresented certain evidence – articles related to the decline in sales from sending out Dear Doctor letters – arguing the articles discussed dispensing rates and not overall sales. Review of the evidence shows that the overall result of the study referenced in the article showed just such a decline: Schedin did not overinflate the findings of the study. (Pl. Ex. 623 ("Results: A highly publicized letter sent in June 1998 was associated with a notable decline (58%) in the concomitant dispensing rate . . . .").) To the extent that dispensing rates differ from sales, the Court finds that reference to dispensing rates in closing argument is not so clearly injurious as to set aside the punitive damages award.

Second, Ortho-McNeil argues that Schedin's discussion of an email newsletter erroneously implied the number of individuals involved in decisions related to labeling of Levaquin. However, review of the exhibit indicates Schedin did not misrepresent the number of people who received the email. (Pl. Ex. 1169.) Further, Schedin's argument about the exhibit related to what was missing from the email – mention of the strengthened warning label for tendon injury – which was probative of his failure to communicate claim. Therefore, the Court does not find Schedin misrepresented evidence such that a new trial is warranted.

In sum, the Court finds that Schedin's closing arguments in the punitive damages phase were not so prejudicial as to warrant a new trial on the punitive damages award. As a result, the Court denies the request for a new trial on the underlying liability.

V. JUDGMENT AS A MATTER OF LAW

Under Rule 50 of the Federal Rules of Civil Procedure, judgment as a matter of law is appropriate if no reasonable juror could return a verdict for the nonmoving party. *Weber v. Strippit, Inc.*, 186 F.3d 907, 912 (8th Cir. 1999). In analyzing a Rule 50 motion, the Court must consider the evidence in the light most favorable to the nonmovant, resolve all factual conflicts in the nonmovant's favor, and give the nonmovant the benefit of all reasonable inferences. *Ogden*, 214 F.3d at 1002. "[J]udgment as a matter of law is proper when the record contains no proof beyond speculation to support the verdict." *Heating & Air Specialists, Inc. v. Jones*, 180 F.3d 923, 932–33 (8th Cir. 1999) (internal quotation marks omitted). "Motions for judgment as a matter of law must meet standards that are more stringent than the standards applied to motions for a new trial." *Spectralytics, Inc. v. Cordis Corp.*, 650 F. Supp. 2d 900, 904 (D. Minn. 2009), *aff'd in part, vacated in part on other grounds by* Nos. 20090156, 2010-1004, 2011 WL 2307402 (8th Cir. June 13, 2011).

The motions brought by Ortho-McNeil for a new trial and for judgment as a matter of law are based on substantially the same arguments. Ortho-McNeil contends Schedin did not show the Levaquin label was inadequate to warn Beecher of the risks of tendon rupture, failed to show Ortho-McNeil had a duty to provide comparative information about other fluoroquinolones, and failed to show with clear and convincing evidence that

Ortho-McNeil acted with deliberate disregard. Since the Court has determined those arguments fail under the less stringent standard of that for a new trial, this Order evaluates only those arguments unique to the judgment as a matter of law motion under the more stringent standard.

In its motions in limine and earlier motions for judgment as a matter of law, Ortho-McNeil argued more extensively that the doctrine of pre-emption applied to many of the arguments made by Schedin on his failure to warn claim because of FDA regulations. Ortho-McNeil re-raises two pre-emption arguments in its third motion for judgment as a matter of law. First, it argues that FDA regulations pre-empt the provision of label warnings that include comparative toxicity. Second, it argues that *Buckman* pre-emption, involving fraud on the FDA, applies to bar Schedin's punitive damages claim. As described earlier, the Court finds the pre-emption analysis of *Wyeth*, as clarified in *Mensing*, is the prevailing legal standard applicable to the instant motions.

A. Comparative Data

In the Court's earlier Order on one of Ortho-McNeil's previous motions for judgment as a matter of law, the Court held that Ortho-McNeil was not impliedly pre-empted from providing comparative data about other fluoroquinolones in the Levaquin label based on differing language between the "[w]arnings and precautions" section of FDA labeling regulations and the "[i]ndications and usage" section. *Schedin*, 2011WL 834020, at *5-6. The latter section requires either an adequate and well controlled study to make a change to a label in that section or a waiver from this requirement. 21 C.F.R. § 201.57(c)(2)(iii). The former section allows a label change in the "[w]arnings and

precautions" section regarding a "clinically significant hazard as soon as there is reasonable evidence of a causal relationship with a drug; a causal relationship need not have been definitively established." *Id.* § 201.57(c)(6)(i).

Ortho-McNeil argues that the portion of the regulation in effect at the time of Schedin's injury would not have allowed comparative representations. The relevant regulation defines an adverse reaction as "an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." *Id.* § 210.57(g) (2005). The regulation goes on to state that "[a]ny claim comparing the drug to which the labeling applies with other drugs in terms of frequency, severity, or character of adverse reactions shall be based on adequate and well-controlled studies . . . unless this requirement is waived . . . ." *Id.* § 210.57(g)(4). As a result, Ortho-McNeil argues the impossibility of a well-controlled comparative study rendered it unable to alter Levaquin's label, pre-empting any duty to provide comparative warnings.

However, in *Wyeth* and *Mensing*, the Supreme Court held that pre-emption only applies to brand-name manufacturers like Ortho-McNeil if there exists "clear evidence that the FDA would not have approved a change to [the drug's] label . . . ." *Wyeth*, 29 S. Ct. at 1198; *Mensing*, 131 S. Ct. at 2581 n.8. As this Court has previously noted:

> Here, both parties concede that a "well-controlled study" as defined by the FDA cannot be conducted ethically since such a study requires a placebo concurrent control group that could be fatal to elderly patients with respiratory infections. Regardless, Ortho–McNeil has presented no evidence that it applied for a waiver from that requirement as the regulation permits.

Schedin, 2011 WL 834020, at *6 (internal citations omitted).

As discussed above in regard to the *Mensing* Court's articulation of the "clear evidence" standard, the Court finds that Ortho-McNeil has failed to show clear evidence that the FDA would have rejected a proposed label change under these circumstances so as to relieve it from state law liability. Ortho-McNeil has provided no evidence that it applied for a waiver from the well-controlled studies requirement and, as such, the requirements of the "demanding defense" of impossibility pre-emption have not been met. *See Wyeth*, 129 S. Ct. at 1199; *Mensing*, 131 S. Ct. at 2581 n.8.

B. Fraud on the FDA

Ortho-McNeil renews its argument that Schedin's punitive damages claim is pre-empted by the fraud on the FDA doctrine as outlined in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The *Buckman* Court held that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. Since policing fraud against federal agencies is not a traditional state function, such claims are pre-empted. *Id.* Ortho-McNeil argues that since Schedin's punitive damages claim rests on a finding that Ortho-McNeil intentionally manipulated the Ingenix study to thwart regulatory action, the claim is one of fraud on the FDA, and thus is pre-empted under *Buckman*.

However, the punitive damages claim, as noted in the Court's previous Order, does not hinge on a defrauding of the FDA. *Schedin*, 2011 WL 834020, at *8. As the Eighth Circuit has recently affirmed, the predicate for *Buckman* pre-emption is that a claim focuses on harm perpetrated against the FDA as opposed to consumers. *Lefaivre v.*

KV Pharm. Co., 636 F.3d 935, 944 (8th Cir. 2011) (addressing adulterated drugs that did not meet current good manufacturing processes). Here the punitive damages claim is based on harm that was visited upon consumers – namely the failure to warn them of the tendon toxicity of Levaquin – in part through alleged manipulation of the Ingenix study. "[S]imply because [that] conduct violates the [Food, Drug and Cosmetics Act ("FDCA")] does not mean a state-law claim based on that same conduct depends on the FDCA's existence[,]" warranting pre-emption. *Id.* (internal quotation marks omitted).

Furthermore, Schedin's punitive damages claim was based on more than just Ortho-McNeil's alleged manipulation of the Ingenix study. As such, even if pre-emption applied to one theory of the claim, it would not foreclose punitive damages on other alleged bases. (*See* Punitive Damages Order, Docket No. 119 ("From Schedin's evidence, . . . a jury could reasonably infer that defendants: had knowledge of or intentionally disregarded medical research regarding Levaquin's tendency to cause tendon injuries, particularly in seniors using corticosteroids; sought to prevent European regulatory action regarding levofloxacin's risks that would negatively impact the drug's reputation; manipulated the Ingenix Study to produce a commercially favorable result; failed to adequately warn Schedin and his doctor of dangers, despite knowing the particular risks of tendon injury Levaquin posed to seniors using corticosteroids, and the higher risk posed by Levaquin as compared to other fluoroquinolones; affirmatively misrepresented Levaquin's safety profile through its marketing campaign and other means.").) As a result, the Court denies Ortho-McNeil's motion for judgment as a matter of law.

ORDER

Based on the foregoing, and the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendant's Motion for a New Trial [Docket No. 224] is **DENIED**.

2. Defendant's Motion for Judgment as a Matter of Law Renewed Motion [Docket No. 219] is **DENIED.**

DATED: August 26, 2011
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge